UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,495	03/31/2004	Sung-Jin Kim	SJKIM-002USC	6449

7663 7590 07/18/2005

STETINA BRUNDA GARRED & BRUCKER
75 ENTERPRISE, SUITE 250
ALISO VIEJO, CA 92656

EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,495	KIM, SUNG-JIN	
	Examiner	Art Unit	
	Susan D. Coe	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10* is/are allowed.

6)☒ Claim(s) *16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed April 21, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

2. Claims 11-15 have been cancelled.

3. Claims 16-20 have been added.

4. Claims 1-10 and 16-20 are pending.

Terminal Disclaimer

5. The terminal disclaimer filed on April 21, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. No. 6,737,087 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

6. Claim 16 is objected to because of the following informalities: in the phrase "an Asiasari Radix extracts," the term "an" is singular while "extracts" is plural. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is confusing because it uses the same letters used in claim 16 to refer to different steps in the method.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Pat. No. 5,889,046.

Claim 17 is directed to an extract composition from Asiasari radix. This claim is a product-by-process claim. Regarding product-by-process claims, note that MPEP § 2113 states that:

> "[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

US '046 teaches an extract from Asiasari radix which is able to protect the brain against hemorrhage and thrombosis (see column 1, lines 55 and 56). The reference extract is extracted

with alcoholic solvents using heat and the solvent is then removed (see column 4, line 31 and column 5, lines 1-11). The reference does not teach extracting using the extract method claimed by applicant. However, the reference extract appears to be identical to the presently claimed extract, based on the fact that the reference extract is from the same plant source as the claimed extract; both the reference extract and the claimed extract are extracted using alcoholic solvents with heat, and both the reference extract and the claimed extract are able to protect the brain. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extract as evidenced by their shared plant source and ability to protect the brain.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

9. Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over KR 2001-0007646 (English translation provided).

KR '646 teaches extracting Asarum sieboldii (Asiasari) using a combination of acetone, chloroform, butanol, isopropyl alcohol, methanol, and ethanol. The plant / solvent mixture is extracted using heat for one to three hours (see page 7 of the translation). The solvent is then evaporated (see page 8 of the translation). The reference does not teach extracting using the extract method claimed by applicant. However, the reference extract appears to be identical to the presently claimed extract, based on the fact that the reference extract is from the same plant

source as the claimed extract and both the reference extract and the claimed extract are extracted using acetone, chloroform, and alcoholic solvents with heat. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extract as evidenced by their shared plant source and shared extraction parameters.

Claim Rejections - 35 USC § 103

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,889,046.

US '046 teaches an Asiasari radix extract. The extract is carried out with solvents such as acetone, methanol, and ethanol (see column 4, lines 31 and 51-52). A specific example of the extraction mixes the plant material with methanol or ethanol at a temperature of 50 degrees Celsius or higher. After the hot solvent is contacted with the plant material, the solution is allowed to extract at room temperature. After extraction, the solvent is removed from the solubilized fraction (see column 5, lines 1-11). The reference does not specifically teach combining the alcoholic solvents with acetone or the length of time of the extraction. However, another example uses acetone extraction and allows the extract to stand overnight (see column 4, lines 53-65). Thus, the reference teaches that both of these extraction procedures is successful in

extracting active ingredients from Asiasari. A person of ordinary skill in the art would reasonably expect that adding acetone to the alcoholic solvents would be a beneficial means of extracting active ingredients from the plant. Based on this reasonable expectation of successful results, an artisan of ordinary skill would be motivated to include acetone with the alcoholic solvents.

The reference also does not specifically teach extracting at all of the times and temperatures claimed by applicant. The specific times and temperatures for an extraction are clearly a result effective parameters that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal extraction times and temperatures in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of extraction time and temperature would have been obvious at the time of applicant's invention.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over KR 2001-0007646.

KR '646 teaches extracting Asarum sieboldii (Asiasari) using a combination of acetone, chloroform, butanol, isopropyl alcohol, methanol, and ethanol. The plant / solvent mixture is extracted using heat for one to three hours (see page 7 of the translation). The solvent is then evaporated to isolate the extract (see page 8 of the translation). The reference also does not

specifically teach extracting at all of the times and temperatures claimed by applicant. The specific times and temperatures for an extraction are clearly a result effective parameters that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal extraction times and temperatures in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of extraction time and temperature would have been obvious at the time of applicant's invention.

12. Claims 1-10 are allowable. Claims 16-20 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe
7-12-05

Susan D. Coe
Primary Examiner
Art Unit 1655